Examination Issues: Immunology

Yvonne (Bonnie) Eyler
Quality Assurance Specialist
Technology Center 1600
USPTO
(571) 272-0871
Yvonne.Eyler@uspto.gov

Written Description

Antibodies

Written Description

35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 ((Fed. Cir. 1991) (emphasis in original).

Claim Set (Noelle)

- "Claim 51. A monoclonal antibody or fragment thereof which specifically binds CD40CR."
- "Claim 52. The monoclonal antibody or fragment of Claim 51, wherein said CD40CR is expressed by activated human T cells."

- Noelle v. Lederman, 355 F.3d 1343, 1346 (Fed. Cir. 2004).

The Specification (Noelle)

- Disclosed isolated mouse CD40CR.
- Disclosed a monoclonal antibody raised to the mouse CD40CR.
- No structural elements of the human CD40CR antigen or the antibody thereto were disclosed.

Written Description Analysis

- "A patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See Enzo Biochem II, 323 F.3d at 965; Regents, 119 F.3d at 1568." Noelle, 355 F.3d at 1350 (Fed. Cir. 2004)

Written Description Analysis

- "[T]he PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." Noelle, 355 F.3d at 1349 (Fed. Cir. 2004) (quoting Enzo BioChem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002).

Written Description Analysis

- "A claim directed to 'any antibody which is capable of binding to antigen X' would have sufficient support in a written description that disclosed 'fully characterized antigens.' Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/menu/written.pdf (last visited Jan. 16, 2003) (emphasis added)." Noelle, 355 F.3d at 1350 (Fed. Cir. 2004).

Written Description Analysis

- "Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." Noelle, 355 F.3d at 1349 (Fed. Cir. 2004) (emphasis in original).

The Decision

- Noelle did not describe human CD40CR antigen.
- Noelle cannot claim an unknown by its binding to an unknown.
- If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen.
- Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen given the state of the art at the time the applications at issue were filed.

Noelle, 355 F.3d at 1349-50 (Fed. Cir. 2004).

Written Description

Antibodies

The Claim

- An antibody that specifically binds an isolated polypeptide that comprises an immunogenic fragment of SEQ ID NO: 1.

The Specification

- Discloses only one species of polypeptide, i.e. SEQ. ID. NO:1.

Written Description

- In this fact pattern, there is adequate written description for antibodies which specifically bind polypeptides comprising SEQ ID NO: 1 but not for the genus of antibodies specifically binding the genus of polypeptides that comprise immunogenic fragments.
- Note that the term comprises opens the claim to include the fragment being embedded in or attached to other nondisclosed polypeptides.

Prior Art

Antibodies

Claim

- An isolated antibody which specifically binds a fusion protein comprising SEQ ID NO: 1.

The Specification

- Discloses an isolated full length polypeptide of SEQ ID NO: 1.
- Discloses an antibody raised to the full length polypeptide.
- Discloses fusion proteins comprising SEQ ID NO: 1 and heterologous polypeptides selected from HIS tags and BSA.

Prior Art

- Reference X teaches antibodies which specifically bind HIS tags for use in protein purification.

Conclusion

- The claim would be rejected under 35 U.S.C. 102 over the prior art reference X antibodies which would specifically bind the instantly claimed fusion protein.

The Claim

- An isolated antibody which specifically binds to a polypeptide comprising SEQ ID NO: 1.

The Specification

- Discloses an isolated full length polypeptide of SEQ ID NO: 1.
- Discloses an antibody raised to the full length polypeptide.

Prior Art

- Reference Y teaches a protein that is 99% identical to SEQ ID NO: 1 over its full length.
- Reference Y also teaches an antibody that was raised to and specifically binds said protein of the art.

Rejection under 35 U.S.C. 102

- Specifically binds, given its broadest reasonable interpretation, defines the act of an antibody binding to its antigen.
- Antibody binding to related antigens is a known characteristic, and is specific for the antibody binding site.
- The antigen of the art is highly related to the antigen used to raise the instantly claimed antibody, indeed, it is nearly identical.
- The antibody of prior art reference Y would support a rejection under 35 U.S.C. 102 over the claimed antibody.